BIOSHIELD II, S. 975: SECTION BY SECTION[1]

Context and Background: Over the last four years we have taken an incremental approach to these preparedness issues. BioShield II intends to address all of the preparedness issues in one bill, obviating the need for enactment of BioShield III, IV, and V. In the current political climate, it's easier to enact big ideas than a series of small ones.

BioShield II provides a comprehensive strategy to address all of the impediments to preparedness for a Bioterror attack or infectious disease outbreak. It also focuses on preparedness for agriculture attacks or outbreaks. It is premised on the concept that if we do not develop the medical countermeasures to prevent infection or treat those who are infected, we risk public panic and massive economic and medical liabilities. We have essentially none of the medical countermeasures we need. In addition, the legislation focuses intently on the development of powerful research tools that will enable us to develop new countermeasures more quickly as these threats evolve. It will be difficult to engage the biopharma industries in the development of these countermeasures and research tools, so the incentives proposed are innovative and aggressive. The legislation also focuses on the critical command and control issues.

Overview: At 29 tiles and 360 pages, BioShield II is comprehensive and complex, but this is what's needed to effectively respond to the nature of these dire threats. To fully understand BioShield II, one needs command of a broad range of disciplines: the science of these evolving threats; zoonotic diseases and bioagriculture threats; biopharma industry economics; procurement, tax, patent, and liability law; FDA, CDC, and EPA regulatory policy; animal models, human clinical trials, adjuvants, and vaccine industry issues; DHS, HHS, and DoD organization and resources; antitrust, export license, and visa law; Nunn-Lugar programs; public health infrastructure and resources; specialized research and manufacturing facilities; international public health agencies; and decontamination science and practice.

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[1] S. 975 was introduced on April 28, 2005, by Senators Lieberman, Hatch, and Brownback.

Titles I, II, and III of S. 975 amend BioShield I, enacted in July, 2004. The purpose of BioShield I is to accelerate the research, development, purchase, and availability of countermeasures to combat bioterrorism threats that could cause public health emergencies affecting national security. BioShield I enacted expedited procedures for the procurement and use of countermeasures and provides for contracts where payment is made if and only if an acceptable countermeasure is developed and delivered. This approach was designed to incentivize for results, not process. It has the contractor fund the research at its own risk and expense with the government paying for results. BioShield II seeks to build on incentives offered in BioShield I to apply its procurement incentives to development of medical countermeasures (defined broadly to include diagnostics, therapeutics, vaccines, research tools, etc.) for all infectious diseases and supplement the procurement incentives with tax, intellectual property and liability incentives to create biodefense, infectious disease, vaccine, and research tool industries that are capable of producing countermeasures as the Bioterror and infectious disease threat evolves.

Sec. 101. Procurement of certain drugs, detection technology, diagnostics, and research tools **p. 7**

Expands the scope of contracts that can be entered into using the expedited procedures and "Special Reserve Fund" established under BioShield I. Whereas BioShield I only permits procurements of certain drugs, devices and biological products to treat, identify or prevent harm from biological, chemical, radiological or nuclear agents, Section 101 of BioShield II also permits procurements of detection technology, diagnostics and research tools (page 7). Amends Homeland Security Act to establish a BioShield "purchase fund" (page 8). HHS may be delegated authority to manage the fund (page 9). Authorizes advance, partial, or progress payments to BioShield contractors (pages 10-12). This is typical of large pharma and small biotech partnerships, where "milestone" payments are made when certain tasks are accomplished. Authorizes use of "other transaction authority" (simplified procurement procedures) (page 13). Sets maximum term of the contract at 10 years, with possible extensions to 18 years (page 14). Authorizes "warm industrial base" fee for firms that maintain a stand-by manufacturing capacity to produce countermeasures (page 15). Presses for single transactions even if additional research and development is necessary (page 18) and procurement of multiple products and technologies to mitigate the risk of dependence on a single supplier (pages 18-19). States that there is no requirement that firms bidding on a contract have secured an IND (FDA authorization to proceed with human clinical trails) (pages 19-20). Authorizes use of "simplified acquisition procedures" (page 20), including authority to limit competition (page 23).

Sec. 102. Additional authority under Project BioShield **p. 29**

This section provides additional authorities to the Secretary of HHS to use in making procurements with the Special Reserve Fund established by BioShield I. Authorizes use of "other transaction authority" for this fund (page 29). Presses for single transactions even if additional research and development is necessary (pages 30-31). States that there is no requirement that firms bidding on a contract have secured FDA approval to launch human clinical trails (an "Investigational New Drug" or IND) (page 31). Clarifies that certain cost accounting regulations do not apply (page 31). Provides for accelerated approval of countermeasures, procurement of multiple products and technologies to mitigate the risk of dependence on a single supplier and a "warm industrial base" fee for firms that maintain a stand-by manufacturing capacity to produce countermeasures (page 32). Clarifies that use of the Special Reserve Fund is not limited to unlicensed countermeasures (page 33). Makes technical amendments to BioShield I to reflect the additional scope of procurements granted by Section 101 of BioShield II (pages 33-35).

Sec. 103. Request of agency **p. 35**

Agencies may submit a request to the Secretary of HHS to utilize the BioShield I and II incentives – procurement, tax, IP and liability – to secure the development of countermeasures to fulfill their mission. Such agencies might include the Department of Defense or Department of Agriculture (pages 35-37). See corollary provisions at page 245 (DoD) and page 359 (EPA).

TITLE II—AMENDMENTS TO THE PROJECT BIOSHIELD ACT OF 2004 REGARDING INFECTIOUS DISEASE COUNTERMEASURES; ADDITIONAL PROVISIONS **p.37**

Sec. 201. Amendments to the Project Bioshield Act of 2004 regarding infectious disease countermeasures **p.37**

Further expands the scope of contracts that can be entered into using the expedited procurement authorities and Special Reserve Fund established by BioShield I, to include countermeasures intended to detect, diagnose, prevent, or treat an infectious disease (pages 37-38).

Sec. 202. Procurement pools; additional incentives under Project Bioshield **p.38**

Provides definitions of important terms used in extending BioShield I. See definition of "infectious disease" at page 42. See also definition of "countermeasure" at page 39, "decontamination technology" at page 40, "diagnostics" at page 42, and "research tool" at page 44.

Sets up "procurement pools" (page 45-47) for infectious disease countermeasures. This may be the best way to proceed in utilizing BioShield for the development of countermeasures where the United States is not the principal

market (e.g. countermeasures for diseases endemic in the developing world). In a procurement pool, a prospective contractor can determine the full extent of the market for the countermeasure and then the United States can add the tax, patent, and liability protections as its principal contributions to the initiative. An advisory committee is established (pages 47-50) to ensure that potential participants in a procurement pool are consulted about all relevant issues.

Applies incentives to the development of "diagnostics" (pages 50-54).

Applies incentives to the development of "research tools" (pages 54-56).

Encourages utilization of "research tools" and waives the substance of NIH Research Tool Guidelines (pages 55-56) that are inconsistent with the commercial interests of research tool companies (which need the right to secure patents, exclusive license and reach-through agreements). See page 242 for similar provision.

Authorizes the development of list of pathogens and agents with respect to which countermeasures will be developed (page 56-57) and includes an illustrative, non-binding list of possibilities (pages 57-62). Permits the government not to publish information about this list consistent with the national security interest (to withhold information that might be useful to terrorists).

Applies incentives to the development of "detectors technology" (pages 64-67).

Applies incentives to the development of "decontamination technology" (pages 67-70).

Directs the Secretary of Homeland Security to enter into negotiations with foreign governments to secure coordination and reciprocity for approving and licensing countermeasures (page 70-71).

Sec. 203. Annual report. **p.71**

Requires the submission to Congress of an annual report regarding impact of incentives in spurring development of countermeasures.

Sec. 204. Use of funds; requirements of manufacturer **p.74**

Provides that the Secretary of HHS may use Special Reserve Fund money for storage, maintenance, security, rotation and transport of any material purchased for the Strategic National Stockpile and shall advise manufacturers of logistical and operational requirements of countermeasures prior to their development and acquisition (pages 74-75).

TITLE III—AMENDMENTS TO THE PROJECT BIOSHIELD ACT OF

2004 REGARDING INCENTIVES TO ESTABLISH BIODEFENSE, INFECTIOUS DISEASE, VACCINE, AND RESEARCH TOOL INDUSTRIES. **p.75**

Subtitle A—Certification of Successful Development **p.75**

Sec. 301. Certification of successful development. **p.75**

Only companies that successfully develop a countermeasure under a BioShield contract are eligible for the incentives in BioShield I and II. The government must "certify" that the company has "successfully" developed the countermeasure (page 77-78 and 82-84).

The government must issue a certification before any patent extension is made available as an incentive (pages 78-82). The patent restoration is available as one incentive, but the patent extension is available only if the Secretary makes the determination described in this section of the legislation. The determination focuses on a number of factors (pages 78-79). A patent extension is not available unless the company develops a new countermeasure (not previously FDA approved) that is clinically superior to existing countermeasures. Re-labeling an existing countermeasure does not qualify. An extension of between 6 and 24 months may be offered as an incentive. If a patent extension is offered as an incentive, the company awarded the contract must provide public written notice of which patent it would extend if it successfully completes the contract. It is not then bound to elect the extension; it may still elect the patent restoration as an incentive. This notice helps the generic pharmaceutical firms to plan their rollout of generic products by avoiding last minute patent extensions. In addition, at the time the contract is awarded, the company must own the patent it later extends (see page 117). This prevents another firm from acquiring the contractor and substituting its patent for purposes of the extension. It can't extend the same patent twice.

Subtitle B—Federal Tax Incentives **p.85**

Sec. 311. General provisions. **p.85**

Provides that firms that enter into BioShield contracts are eligible for tax incentives. They must elect one of five tax incentives. They may elect different tax incentives for different contracts. The tax incentives are available even if the company is not able to complete the contract and qualify for the procurement, intellectual property and liability incentives discussed below.

This section enacts two of these tax incentives: R and D Limited partnership and special capital gains incentives, both of which are focused on small firms that do not have tax liability with respect to which to claim a tax credit. These two incentives go to investors, not the contractor, and help the contractor to form

capital to fund the R&D to complete the contract. A third tax incentive for these firms is included in Section 312 (see pages 100-108) (New Market Credit). A research and development partnership (311(a) (1)) (page 85) is an investment pool to fund R&D with the tax credits and deductions that would normally accrue to the company flowing to the investors instead. Such pools were common in 1981-1986 when they were abolished in the 1986 Tax Reform Act. The capital gains incentive enables small firms to issue a separate class of stock to fund the R&D with the investors in that stock receiving a zero capital gains rate upon the sale of the stock. The current capital gains tax rate for all investments is 15%.

Sec. 312. Tax credits. **p.88**

This section enacts three tax credits – two for companies and one for investors. The two for companies are found in Section 312(a) (1) (page 88) and Section 312(a) (2) (page 94). Tax credits reduce the tax liability of firms that incur tax liability. These credits are greater than the current R&D Tax Credit. The first is a credit for research performed in-house at the company and the second is for research performed at an academic medical center. The third credit is found in Section 312(a) (3) (page 100) and it's a credit for investors based on the value of their investment – a New Market Credit. Other new market credits exist, specifically the New Markets Tax Credit (NMTC) Program that permits taxpayers to receive a credit against Federal income taxes for making qualified equity investments in designated Community Development Entities (CDE's).

Subtitle C—Patent Protections **p.108**

The patent incentives in BioShield II are available only to companies that successfully complete the contract. The standards and procedures to secure a certification for successful development are presented at pages 75-78.

Two forms of patent incentives are available, patent restoration (Section 331(b)) and patent extension (Section 331(c)). A firm must elect between them and cannot qualify for both. Different firms will elect one or the other incentive, depending on a variety of factors...

Sec. 331. Patent term restoration and extension and exclusive marketing. **p.108**

Patent term restoration (subsection (b)) (page 109) permits a successful contractor to secure full restoration of any term lost for the patent on the countermeasures it's developed. This will give the contractor on the date of FDA approval of the countermeasure a patent with the same term as initially set when the patent was issued by the Patent and Trademark Office. All erosion of the patent from the date of issuance to the date of FDA approval is restored.

Patent term extension (subsection (c)(page 116) permits a successful contractor

to secure up to two years extension of any patent its portfolio at the time the contract was awarded. This option is available only if the HHS Secretary determines that this patent extension is needed – see criteria for this determination at pages 78-82.

Subsection (d) (page 122) permits the government to waive "march-in" rights on a patent it has licensed to the contractor. The government may not now waive such rights. March-in rights permit the government under terms that are not well defined to cancel a license and secure full ownership of the patent from the contractor. The possible use of these march-in rights deters many companies from entering into contracts with the government.

Subsection (e) (page 124) gives the contractor 10 years of control of the clinical trial data upon which it secured FDA approval for the countermeasure (up from 5 years under current law). This means that a generic pharmaceutical firm may not rely on this data to secure approval of a generic version of the countermeasure during this period.

Sec. 332. International protection for BioShield intellectual property. **p.126**

Directs the Secretary of Commerce, U.S. Trade Representative and Commissioner of Patents in international, bilateral, and multilateral negotiations to protect patents on countermeasures from impairment.

Subtitle D—Liability Protections **p.127**

The liability incentives in BioShield II are available only to companies that successfully complete the contract. The standards and procedures to secure a certification for successful development are presented at pages 75-78.

Sec. 341. Liability and compensation for injured parties. **p.127**

Liability protection is granted during human clinical trials of a countermeasure even if the company is not finally certified as having successfully developed a countermeasure (page 130, lines 5-13). See pages 186-188. concerning liability protection for health care personnel.

While the SAFETY Act can provide significant protections to a company, its application in the context of countermeasures against bio-terrorism is extremely limited. Most significantly, the potential liability of a provider of anti-terrorist technologies that may allegedly cause injury "prior" to a terrorist attack, such as a vaccine, are not currently addressed by the SAFETY Act. This limitation of the SAFETY Act leaves providers of anti-terrorism vaccines without any adequate protections aside from the possibility of Federal indemnification under Public Law No. 85-804. BioShield II would cure this problem by making SAFETY Act liability protections available in lawsuits involving death or

injuries caused by deployment of qualified anti-terrorism technologies against the potential threat of a terrorist act (pages 134-135).

The liability provisions of BioShield only apply to BioShield contracts. They have no impact in any other context and have no impact on any pending litigation in another context. **p.136**

TITLE IV—VALLEY OF DEATH FOR SMALL COMPANIES **p.136**

Sec. 401. Purpose. **p.136**

Small companies refer to the "valley of death" as the period from their founding through to the development of a prototype product they can manufacture or through securing FDA approval to proceed with human clinical trials (an IND). This is the period in which it is difficult to for them to secure the capital from investors to fund their R&D. The purpose of this title is to provide funding to these firms to ensure that they are able to bid on a BioShield contract. If they are awarded a contract, they are generally able to secure the capital from investors to complete the contract.

Sec. 402. Valley of Death for Small Companies **p.136**

Enacts new subsections (l) through (p), each of which authorizes reimbursement of small firms for various expenses.

TITLE V—BIOSHIELD ANTITRUST EXEMPTION **p.140**

Sec. 501. Limited antitrust exemption. **p.140**

Companies that wish to collaborate in the development of a countermeasure may secure protection from the antitrust laws.

TITLE VI—BIOSHIELD IMMIGRATION PRIORITY **p.151**

Sec. 601. H1B visa exemption. **p.151**

States that foreign nationals who are employed by companies that enter into BioShield contracts do not count against the cap on H1B visas. The provision does not change the standard of which employees qualify for this visa.

Sec. 602. Visa processing.

Provides for expedited processing of these H1B visa applications.

TITLE VII—BIOSHIELD EXPORT PRIORITY **p.153**

Sec. 701. Short title. **p.153**

Sec. 702. Requirement to expedite export applications. **p.154**

Provides for expedited review of export licenses of companies that enter into BioShield contracts. The provision does not change the standard of which exports meet the statutory standard.

Sec. 703. Preservation of foreign sales markets for qualified and security countermeasures. **p.155**

Provides that the U.S. government should not undermine the markets of BioShield contractors by selling the countermeasures it's procured to U.S. allied governments or commercial entities that might otherwise purchase the countermeasure from the BioShield contractor.

TITLE VIII—OFFICE OF PUBLIC HEALTH COUNTERMEASURE DEVELOPMENT **p.156**

Two priority issues in BioShield II are which agency is responsible for securing the development of countermeasures (utilizing the procurement, tax, patent, and liability incentives) and which agency is responsible for managing the government's response to a public health or similar emergency. Titles VIII, IX, and X address these issues.

Sec. 801. Office of Public Health Countermeasure Development. **p.156**

The legislation establishes the Office of Public Health Countermeasure Development in HHS to be led by an Assistant Secretary. The office is responsible for developing a national preparedness plan with regard to countermeasure development.

Sec. 802. Bioterror, chemical, nuclear, radiological, and infectious disease countermeasure development strategy. **p.158**

The countermeasure development strategy shall be developed in consultation with the Secretary of DHS and DoD (page 158). It shall focus on engaging the private sector in these development priorities. All of the relevant entities shall be consulted in developing the strategy (page 160-161). The strategy shall focus on the engaging the entrepreneurial private sector (page 161-163). The plan shall designate in five year increments the countermeasures the government seeks to procure (page 163). It shall plan to procure at least four countermeasures for infectious diseases for every five for Bioterror (page 164-165). It shall focus on procuring research tools (page 165). Performance measures shall be set to determine the effectiveness of the strategy (page 165-167). An advisory committee is established for these issues (page 167-171).

TITLE IX—OFFICE OF MEDICAL READINESS AND RESPONSE OF THE DEPARTMENT OF HOMELAND SECURITY **p.172**

Establishes within DHS an Office of Medical Readiness and Response, lead by an Assistant Secretary that reports to the Secretary of DHS, to coordinate any/all medical/public health issues (strategy, training/exercises, interagency coordination, funding and implementation) around the federal medical response and the federal support to State and Local agencies for mass casualty care.

Sec. 901. Office of Medical Readiness and Response of the Department of Homeland Security. **p.172**

DHS Assistant Secretary for Medical Readiness and Response serves as the Secretary's principal advisor and DHS' primary official for medical preparedness and response. Consolidates existing DHS medical/health programs, including the National Disaster Medical System, Metropolitan Medical Response System, the emergency medical response functions of the Office of Emergency Preparedness (pursuant to section 503(5)), and other resources and Offices as designated by the Secretary.

TITLE X—NATIONAL EMERGENCY MEDICAL READINESS AND RESPONSE BOARD **p.175**

Sec. 1001. National Emergency Medical Readiness and Response Board. **p.175**

This Board, which is chaired by the DHS Assistant Secretary for Medical Readiness and Response, and includes the Nation's Senior Medical Officials, is responsible for overseeing the development, assessment and validation (through joint exercises) of the national interagency plans for the Federal emergency medical response, in support of and coordination with the State and Local response, to events of National Significance. An Advisory Committee to this Board will be established, consisting of a broad representation of local/state/national/international medical and health officials.

TITLE XI—ENCOURAGING GREATER COORDINATION WITH FORMER SOVIET SCIENTISTS AND TRANSFER OF COUNTER-MEASURES **p.181**

Sec. 1101. Purpose; report to Congress. **p.181**

Directs the State and Commerce Departments to recommend additional steps to secure access to the Bioterror pathogens developed by the former Soviet Union and to secure intellectual property protections that will facilitate development of countermeasures to these pathogens.

submitted to Congress within one year of enactment of this Act.

TITLE XIV—CONSTRUCTION OF SPECIALIZED RESEARCH FACILITIES FOR THE DEVELOPMENT OF COUNTERMEASURES
TITLE XV—BIODEFENSE AND INFECTIOUS DISEASE RESEARCH AND SCIENTIFIC AND TECHNICAL PERSONNEL **p.191**

Sec. 1501. Establishment of grant program. **p.195**

Establishes a CDC grant program and scholarships to eligible entities to ensure that sufficient scientific and technical personnel are available to conduct biodefense and infectious disease research.

TITLE XVI—NATIONAL INSTITUTES OF HEALTH **p.202**

The National Institutes of Health sponsors basic research through intramural and extramural programs. This basic research is licensed to biopharma companies – under the Bayh-Dole Act – for development into medical products. Patents are what is licensed and if the patents become products, the company pays royalties back to NIH or the extramural program entity on the sales of that product. So, the effectiveness of this tech transfer effort is critical to the translation of the government funded basic research into healthcare products at the bedside. BioShield II proposes to strengthen these technology transfer mechanisms to increase the likelihood that the government's investment will provide benefits to patients. The legislation does not propose to change the terms under which NIH funds basic research or the peer review process or otherwise attempt to convert NIH into a technology development agency. The legislation applies to all NIH funded research, not just that related to Bioterror or infectious disease agents. It makes no sense to strengthen the technology transfer mechanisms for only a small subset of NIH funded research.

Subtitle A—National Center for Healthcare Technology Development **p.202**

Sec. 1601. Purpose. **p.202**

Improve technology transfer to accelerate development of technologies for patients.

Sec. 1602. National Center for Healthcare Technology Development. **p.202**

A Center will be established within the NIH called the National Center for Healthcare Technology Development whose purpose will be to maximize and accelerate technology development throughout all of the other Centers and Institutes of the NIH. Central to its mission will be to ensure that Federal Government research is not in conflict with private research, and that all efforts are made to accelerate the production of products from basic research.

There will be an Assistant Director for Biological, Chemical, Radiological and Infectious Disease Countermeasure Development within the Center. There will be annual report to Congress from the Center providing a national strategy for tech transfer, partnership and other healthcare technology development.

A National Advisory Council, appointed by the Director of the Center, comprised of representative members of the biotech, pharmaceutical, diagnostic, research tool, regulatory, financial, and business interests will advise the Center Director on matters pertaining to the acceleration of product development. Additional councils comprised of industry experts, linked to each of the NIH Institutes and Centers, will likewise provide practical, comprehensive input regarding product development arising from respective specialty disciplines. Councils will also facilitate communication and cooperation between and among Institutes and Centers.

Two annual awards are offered, one the Birch Bayh and Robert Dole Award for Healthcare Partnerships, and the other the Ronald Reagan and Morris Udall Award for Healthcare Technology Development. Other elements include oversight instructions for SBIR and STTR programs and grants.

Authorization is given to appropriate an amount equal to "0.3 percent" of the total for NIH appropriations to staff the technology partnership function.

Sec. 1603. Technology development opportunities assessments **p.224**

This section calls for every proposal submitted to NIH for funding to include an evaluation of the proposed research's potential utility to the development of health care technology for the benefit of patients. This is a procedural requirement that does not change the standard for judging which grants are issued. It does not make "utility" a standard for ranking the proposals. Nothing in this legislation places industry experts on the peer review panels to judge the grant applications. This section simply asks the applicant to provide whatever information they posses about the potential utility of the research to patients.

Sec. 1604. Resources for the National Center for Healthcare Technology Development. **p.225**

Directs the Center to develop programs to speed the development of technology for the benefit of patients.

Sec. 1605. Biennial report of the Director of the National Institutes of Health to the President and Congress. **p.226**

NIH Director to document the technology that has been developed utilizing NIH funded research.

Sec. 1606. Authority of the Directors of the National Research Institutes; biennial report. **p.227**

NIH Directors given authority to expand knowledge about the creation, manufacture and administration of treatments to patients. The institutes are directed to document their contributions to technology development in reports.

Sec. 1607. Commercial research and investigations. **p.229**

Broadens mandate of NIH to include technology development for the benefit of patients.

Sec. 1608. SBIR/STTR program consultation with the Director of the Center of Healthcare Technology Development. **p.229**

Gives new Center a role in administration of SBIR/STTR programs.

Sec. 1609. Purpose of the National Research Institutes. **p.230**

Expands purposes of NIH institutes to include technology development for the benefit of patients.

Sec. 1610. Conforming amendment. **p.234**
Sec. 1611. Effective date. **p.234**

Subtitle B—Protecting Government Investment in Basic Biomedical Research **p.234**

Sec. 1621. Findings. **p.234**

Because patents lie at the core of the technology transfer process, BioShield II proposes to enhance the value of the patents that NIH and its grantees secure. The legislation proposes to provide full patent term restoration for all patents that arise from NIH funded research.

Sec. 1622. Utilization and availability. **p.235**

This section waives the substance of the NIH Research Tool Guidelines IOof NIH Research Tool Guidelines that are inconsistent with the commercial interests of research tool companies (which need the right to secure patents, exclusive license and reach-through agreements). See page 55-56 for a similar provision in the context of infectious disease countermeasure development.

Sec. 1623. Restoration of term of unexploited patents on Government sponsored inventions relating to countermeasures. **p.236**

This protection against erosion is identical to that provided in Section 331(b) (page 109) above. Patent term restoration permits an NIH or extramural licensee to secure full restoration of any term lost for the patent on the countermeasures it's developed. This will give the contractor on the date of FDA approval of the countermeasure a patent with the same term as initially set when the patent was issued by the Patent and Trademark Office. All erosion of the patent from the date of issuance to the date of FDA approval is restored. This measure will dramatically increase the effectiveness of the technology transfer programs at NIH and the extramural grantees. It sill answer the question many are asking about the rationale and benefits to patients of the doubling of NIH appropriations.

Subsection (d) (page 241) permits the government to waive "march-in" rights on a patent it has licensed to the contractor. The government may not now waive such rights. March-in rights permit the government under terms that are not well defined to cancel a license and secure full ownership of the patent from the contractor. The possible use of these march-in rights deters many companies from entering into contracts with the government. See similar provision on page 122.

Sec. 1624. Encouraging the patenting of research tools. **p.242**

This provision dovetails with the provision cited above that waives the NIH Research Tool Guidelines, which are anti-patenting of research tools.

Sec. 1625. Effective date. **p.242**

The effective date is set at October 1, 2005 or date of enactment, whichever comes later.

Subtitle C—Partnership Challenge Grants **p.242**

Sec. 1631. Partnership challenge grants. **p.242**

This provision authorizes a program that currently exists at NIH to provide matching grants to companies to develop technology and countermeasures for and research tools.

TITLE XVII—DEVELOPMENT OF COUNTERMEASURE RESEARCH AT THE DEPARTMENT OF DEFENSE **p.244**

Sec. 1701. Development of countermeasure research at the Department of Defense. **p.244**

The Department of Defense has attempted to develop many countermeasures

but, due to an absence of industry interest, has not been able to secure final approval for the products for use as countermeasures. This provision authorizes appropriations to DoD to complete this work.

Sec. 1702. Request by the department of defense. **p.245**

DoD is authorized to request to utilize the incentives – procurement, tax, patent, and liability - in BioShield I and II to secure the development of these countermeasures. See Section 103 above (page 35).

Sec. 1703. Expanded public-private partnership agreements for research and development. **p.246**

Authorizes DoD to enter into Cooperative Research and Development Agreements (CRADAS) similar to those at NIH. In these arrangements government funded scientists and industry scientists work together on a common research agenda, sharing resources, and exchanging information. These arrangements may lead to patents and licensing of patents under the Bayh-Dole Act.

TITLE XVIII—MILLENNIUM MEDICINE DISCOVERY AWARD **p.252**

Sec. 1801. Millennium Medicine Discovery Award. **p.252**

Supplementing the procurement, tax, patent, and liability incentives, this section authorizes the government to establish a prize reward for the development of certain critical medical countermeasures, such as an anti-viral that kills the AIDS virus. The awards could be up to $100 million for each countermeasure.

TITLE XIX—FOOD AND DRUG ADMINISTRATION **p.255**

Sec. 1901. Other incentives. **p.255**

Grants accelerated approval of countermeasures by the FDA, including countermeasures approved under its animal model rule.

Sec. 1902. Systems biology. **p.256**

The Secretary of HHS is to integrate the application of computational tools used to understand the dynamic behavior of biological networks into research programs as described in the “Critical Path Initiative” FDA report 3/04. This computer modeling will facilitate the development of tools and methods useful in the evaluation and approval of countermeasures.

Sec. 1903. Bioterror and infectious disease provisions **p.258**

Contains the definitions of biological agent, bioterror, countermeasure and infectious disease. A new office of Deputy Commissioner for Biological, Chemical, Nuclear, Radiological and Infectious Disease Products is established to oversee the evaluation of countermeasures within the agency. The Deputy Commissioner will have the authority to increase staffing and funding for a given project, and will have authority to waive user fees. Should a threat be eminent, the Secretary may declare a countermeasure a "fast track" product for expedited FDA review, and may waive user fees.

Sec. 1904. Approvals of certain drugs based on animal trials. **p.263**

The Secretary may grant approval based on animal studies, and may establish regulations, criteria and procedures for animal trials that substitute for human clinical trials. (reviewed under Title XX Animal Models).

Sec. 1905. Clinical trial guidelines for anti-infectives. **p.265**

Those developing anti-infective technology need to know early in development what the requirements for data and trials will be from FDA. The protocols need to be standardized, not individualized for each case. Within one year of enactment, the Commissioner of FDA is requested to establish guidelines for anti-biotic or anti-microbial clinical trials and submissions, and again within five years and every five years thereafter, taking technological advancements into account.

Sec. 1906. Authorization of appropriations for FDA purchase of microbiological data. **p.266**

$3 million authorized for the collection of nationwide laboratory data to address growing resistance to antibiotics.

Sec. 1907. Authorization of appropriations to implement Public Health Service action plan to combat antimicrobial resistance. **p.266**

$25 million authorized for implementation of existing action plan to combat growing resistance to antimicrobials through education, surveillance, and regulation.

TITLE XX—ANIMAL MODELS **p.267**

Real and anticipated bioweapons involve the use of rarely encountered, highly infectious, often lethal agents. It would be highly unethical to test supposedly protective new drugs or vaccines in humans, because if the new product failed, the person(s) would succumb to a terrible illness. Because of such circumstances, the FDA has adopted the Animal Rule, allowing the substitution

of appropriate animals for efficacy testing of countermeasures in clinical trials. This presupposes that there is excellent correlation between a laboratory animal's response to a disease agent and a medicine or vaccine and that of a human. The guarantee that this relationship exists between one animal species and humans requires careful study and analysis. The current lack of animal model research represents a true bottleneck that will limit the testing and approval of bioweapons countermeasures.

Sec. 2001. Working Group. **p.267**

Establishment of a working group to identify scientific gaps in the study of animals' physiological responses and their link to human responses to disease agents. A well-characterized animal is what makes the FDA's Animal Rule practicable. Grants are provided to eligible entities for identification and development of animal models for certain diseases.

Sec. 2002. Animal models five-year initiative. **p.271**

Animal models five-year initiative provides funding for expansion of National Primate Research Centers to improve facilities, upgrade care and breeding programs and enlarge capacity in order to address the increased demand for non-human primate models for countermeasure research.

TITLE XXI—STRENGTHENING OF THE VACCINE INDUSTRY **p.274**

Subtitle A—Biologics, Adjuvants, and Cell Culture Development **p.274**

Sec. 2101. Biologics manufacturing capacity incentives. **p.274**

Secretary of HHS is to survey biologics/countermeasure manufacturing facilities and develop a plan to ensure sufficient capability is available in the US, Canada , Mexico, Europe and Japan – and to consider funding for construction and maintenance of needed facilities. The plan is to be submitted to Congress.

Sec. 2102. Biologics manufacturing efficiency incentives. **p.276**

Biologics manufacturing efficiency incentives for new technologies that increase output capacity and purity, and reduce costs.

Sec. 2103. Development of vaccine adjuvants.

Calls for priority handling procedures from HHS and FDA to accelerate development and approval of novel vaccine adjuvants, a shortage of which slows new vaccine development and approval. Liability protections are extended to adjuvants when used as part of BioShield countermeasure products. **p.280**

Sec. 2104. Cell culture or recombinant vaccines. **p.283**

NIH, FDA and CDC are asked to improve regulations, develop a strategic plan, and award grants to incite the development of new vaccine production technologies.

Subtitle B—Influenza Vaccine **p.285**

CHAPTER 1—INFLUENZA VACCINE AWARENESS CAMPAIGN **p.285**

Sec. 2111. Awareness campaign and education and outreach efforts. **p.285**

Establishes a public awareness campaign and education and outreach efforts on the importance of receiving the influenza vaccine and the recommendations of who should be vaccinated.

CHAPTER 2—ENCOURAGING VACCINE PRODUCTION CAPACITY **p.287**

Sec. 2121. Incentives for the construction of vaccine manufacturing facilities. **p.287**

Establishes a tax credit of 20% to encourage vaccine and biotechnology companies to invest in the construction of new or to renovate existing facilities in the U.S. and for the production of new and improved vaccines. The tax credit would exist for five years.

CHAPTER 3—ENSURING SUFFICIENT FLU VACCINE SUPPLY **p.290**

Sec. 2131. Vaccine supply. **p.290**

Establishes a government fallback purchase guarantee program to remove manufacturing disincentives. Each year, HHS would guarantee to purchase a specific number of doses at the end of the flu season to ensure sufficient vaccine production to protect the U.S. population. HHS would negotiate an equitable rate with manufacturers below market value to purchase unused vaccine up to the number of doses guaranteed at the end of the season.

CHAPTER 4—PREPARING FOR A PANDEMIC OR EPIDEMIC **p.292**

Sec. 2141. Preparation for influenza pandemic or epidemic; anti-virals supply. **p.292**

Provides funding for research into improved vaccine technologies, and requires the development of a protocol to disseminate the vaccine to those who need it the most in an emergency. Requires HHS, acting through the Director of the National Vaccine Program and in consultation with CDC, to implement a

protocol if the flu reaches epidemic or pandemic levels. CDC would be required to use funds provided to address a variety of pandemic preparedness issues. Authorizes $150 million a year for five years for these purposes.

Requires the Secretary of HHS to establish a stockpile of anti-viral medications, in sufficient quantity to treat not less than 2% (should read 20) of the U.S. population, for rapid response to an influenza outbreak.

CHAPTER 5—REPORT AND ADMINISTRATION **p.295**

Sec. 2151. Report to Congress. **p.295**

Director of CDC will assemble a report describing the state of the science of compounds that reduce complications of excessive immune response.

Sec. 2152. Simplified administration of vaccine supply. **p.296**

Gives the Secretary of HHS vaccine buy-sell authority.

Sec. 2153. Medicare coverage of vaccines and prophylaxis as countermeasures. **p.296**

The public interest would be served best by extending Medicare Part B coverage and reimbursement to vaccines and prophylaxis against influenzas, chemical and biological agents, toxins and radiological materials to encourage voluntary vaccination and treatment. The Social Security Act shall be amended to accommodate this public good.

TITLE XXII—GAAP ACCOUNTING FOR VACCINE REVENUE RECOGNITION **p.298**

Sec. 2201. GAAP accounting for vaccine procurement. **p.298**

New rules at the Securities and Exchange Commission regarding recognition of revenue by companies are proving to be problematic in the specialized context of vaccine manufacturing and distribution. This is a problem that needs to be solved so that vaccines can be made available to those in need. This section presses the SEC and HHS to work out an agreement that enables vaccine manufacturers to recognize revenue at the appropriate time. This can be accomplished through SEC "safe harbors" or modification of the HHS vaccine contracts.

TITLE XXIII—HUMAN CLINICAL TRIALS AND DRUGS FOR RARE DISEASES AND CONDITIONS **p.299**

Sec. 2301. Expanded human clinical trials qualifying for orphan drug credit. **p.299**

This section specifies that the date on which tax credits are available for developers of orphan drugs starts on the date they apply for designation of the drug as an "orphan disease" assuming that the designation is eventually secured. This eliminates a current disincentive to commence clinical trails on these drugs prior to this designation. The tax credits for this research is now only available after the date of the designation.

TITLE XXIV—HEALTHCARE SYSTEM COLLECTION OF CLINICAL DATA REGARDING SAFETY AND EFFECTIVENESS OF COUNTER-MEASURES **p.301**

Sec. 2401. Findings; definitions. **p.301**

If and when a medical countermeasure is deployed in response to a Bioterror attack or infectious disease outbreak, we need to secure in real time data on the effectiveness and side effects of the countermeasure. In many cases, these countermeasures will have been approved based on animal models, not human clinical trails. The first opportunity to determine the safety and effectiveness of the product might be when the countermeasure is first deployed in a public health emergency.

Sec. 2402. Certification of clinical countermeasures delivery centers. **p.303**

The legislation establishes qualifications for hospitals that have the capacity to conduct these clinical trails and secure this critical data.

Sec. 2403. Eligibility criteria. **p.306**

The eligibility criteria focus on highly specialized hospitals.

Sec. 2404. Policies, procedures, and protocols for the delivery of clinical countermeasures. **p.308**

The certified centers shall establish plans and protocols for the conduct of these clinical trials.

Sec. 2405. Incentives for qualified clinical countermeasures delivery centers. **p.310**

Incentives are provided to these centers for their participation in this program.

Sec. 2406. Authorization of appropriations. **p.314**

Such sums are authorized for this program.

TITLE XXV—CENTERS FOR DISEASE CONTROL AND **p.314**

PREVENTION

Sec. 2501. Global Disease Detection Trust Fund. p.314

To ensure adequate funding for critical global disease detection functions, the bill establishes a Global Disease Detection Trust Fund at CDC$1.25 billion.

Sec. 2502. Environmental microbiology facility study and report. p.317

Tasks CDC to conduct a study on the feasibility of developing a microbiology facility at Fort Dietrick.

Sec. 2503. Enforcement of quarantines. p.317

Raises the current penalties for violating a quarantine from $1000 and up to 1 year in prison to $250,000 and up to 10 years in prison. Tasks CDC to evaluate the qualifications of physicians who conduct health screenings on aliens seeking temporary or permanent residence in the United States.

Sec. 2504. Educational campaign at the Centers for Disease Control and Prevention. p.318

Tasks CDC, in conjunction with other agencies to carry out a two-phase national education campaign regarding public health measures that might be implemented in the event of a pandemic outbreak or Bioterror attack. Compliance with these public health measures may increase if the public understands the nature and terms of such measures, including quarantines and isolation.

TITLE XXVI—ZOONOTIC DISEASE SURVEILLANCE p.322

Because more than 70 percent of known bioterror agents and newly emerging infectious diseases primarily infect animals (zoonoses), many have the ability to infect wildlife, livestock, and pets. Increased surveillance of all animal populations for illnesses that may infect humans is a wise investment towards prevention. Improved surveillance and reporting through the real-time networking of human and animal laboratories will go far to provide an early alert mechanism to inform public health officials.

Sec. 2601. Zoonotic Disease p.322

A Zoonotic Disease Working Group shall be established within DHS to evaluate the integration of human and animal zoonotic disease networks. Existing laboratories have limited crossover, and most emerging infectious diseases originate in animals. Private sector shall be included in the working group, and a report shall be submitted to DHS within 8 months to include recommendations for funding and change.

TITLE XXVII—COUNTERMEASURES AGAINST AGROTERRORISM p.325

BioShield II focuses on preparedness for both natural and Bioterror pathogens affecting humans. This title focuses on preparedness for both natural and Bioterror pathogens affecting animals and plants. Many of the policy issues that arise in the human framework also arise in the context of bioag. There is obvious synergy in applying the legislation to both types of threats.

Sec. 2701. Findings. p.325

The US could suffer severe economic loss if our agricultural establishment were attacked. We are particularly vulnerable because of our uniquely intensive and concentrated methods of practice conducted by agribusinesses. We suffer from insufficient surveillance, a declining pool of diagnosticians, inadequate laboratories, and deficient livestock tracking.

Sec. 2702. Definitions. p.328

Agriculture includes the production of food, feed and fiber, and its marketing, distribution and use.

Sec. 2703. Establishment of Working Group. p.331

Cooperative working group established, including USDA, CDC, Center for Veterinary Medicine at FDA and the Animal Health Institute.

Sec. 2704. Duties of the Working Group. p.332

To include study of our preparedness, the availability of countermeasures, the appropriateness of borrowing BioShield tax, liability and patent incentives for development of countermeasures, trade agreements with countries that suffer exotic animal diseases, new vaccine techniques, new uses for Plum Island Research Center, and to make recommendations accordingly. The Working Group shall report to Congress in 1 year.

Sec. 2705. State and local assistance in implementing strategies p.335

The Secretary of Agriculture is asked to evaluate the availability and best use of expertise throughout all public agencies. This would include epidemiologists, animal and plant pathologist, and those trained to identify foreign animal diseases. Grants for education of farmers, ranchers, and emergency responders about biosecurity are authorized.

Sec. 2706. Interagency coordination. p.340

DHS is to establish a senior level position at FEMA to liaison with DHS, FEMA, USDA, the Department of Transportation, state agencies and tribal governments. HHS is to appoint a senior liaison to work with the animal health, emergency management, tribal government, and industry communities.

Sec. 2707. Regional, State, and local preparedness. **p.342**

The EPA, USDA, and FEMA will coordinate and develop best practices for response to an agroterror event within their respective jurisdictions throughout all levels of response.

Sec. 2708. International activities. **p.344**

Should an outbreak of a significant agricultural disease occur in a foreign country, either by human intention or natural occurrence, the Secretary of Agriculture must have a plan for both cooperating and assisting the affected country, and also for protecting our borders. Assistance may include training within the US for veterinarians to improve diagnosis, or the training of foreign personnel by our specialists. We may loan personnel, expertise, and resources to a foreign outbreak.

Sec. 2709. Review of legal authority. **p.346**

The Attorney General needs to conduct a review of State and local laws to determine if laws exist that could interfere with a response plan. The AG will report to Congress with in 180 days.

TITLE XXVIII—GLOBAL DISTRIBUTION OF MEDICAL COUNTERMEASURES. **p.347**

If BioShield I and II are effective in securing the development of medical countermeasures for Bioterror and infectious disease pathogens, we need to be ready to distribute these countermeasures to those who need them.

Sec. 2801. Findings. **p.347**

USAID, in cooperation with a dozen other agencies, is tasked to provide a recommended strategy for the distribution of medical countermeasures, including distribution to populations in the Developing World. **p.348**

TITLE XXIX—ENVIRONMENTAL PROTECTION AGENCY; DECONTAMINATION AND REMEDIATION **p.355**

Sec. 2901. Findings. **p.355**

Sec. 2902. Report on capabilities. **p.356**

In addition to effective countermeasures for the development of medical countermeasures for Bioterror and infectious disease pathogens, we need to be able to decontaminate the facilities that may be affected. The Environmental Protection Agency, in consultation with other agencies, is tasked to report on the state of decontamination technology and make

recommendations for action. EPA is authorized to submit a request to the Secretary of HHS to utilize the BioShield I and II incentives – procurement, tax, IP and liability – to secure the development of decontamination countermeasures to fulfill its mission. See page 35 and 245 (DoD).